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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,723	12/06/2001	Mark G. Allen	BVTP-P04-506	4309

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ROPES & GRAY LLP
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EXAMINER	
WITCZAK, CATHERINE	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

CT

Office Action Summary	Application No.	Applicant(s)	
	10/010,723	ALLEN ET AL.	
	Examiner	Art Unit	
	Catherine N. Witczak	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 49-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 49-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

10/26/07

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/9/2007 has been entered.

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/095221, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The above mentioned application contains to reference to either substrate and/or the microneedles being formed with flexible materials. Accordingly, the claims are not entitled to the benefit of the 6/10/1998 filing date. The priority date for pruposes of examination will be considering to be the filing date of application 09/316,229, filed 5/21/1999 of which the present application is a continuation of.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant claims that the substrate and/or the microneedles are formed from flexible material to allow the device to fit the countour of the biological barrier. This recitation is not enbalbed as the specification provides no detals as to what Applicant considers such flexible materials.

As applicant argues that (see Remarks, 10/9/2007) "certain plastic materials may be made flexible .. but may also be made literally indestructible ... and certainly would not 'allow the device to fit the contour of the biological barrier." Applicant further goes on to argue that "contrary to evidence Applicants provided herein, the Examiner has cited no reference to supports the assertion the 'polyethylene, PTFE, etc.. are well known to be flexible'" In response to this, Examiner points to page 7 of the Remarks, where Applicant submits that both polyethylene and PFTE can be made flexible or non-flexible.". Examiner is confused as to the Applicant's position, as on one hand Applicant argues that there is sufficient enablement as to what a "flexible" material is, but at the same time, all of Applicant's arguments seems to point away from this conclusion, as Applicant has themselves admitted that certain plastic materials may be flexible or non-flexible in different situations, and has argued that PTFE is not necessarily known to be flexible, while at the same time claiming that PTFE is a flexible material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 49-70 rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al (US 3,964,482) as modified by Thompson (US 6,669,663) .

Gerstel et al disclose in column 7, lines 52-68 the microneedle having a length between 1um and 1mm and a diameter between 1um and 100um with an annular channel extending from the base to the tip (Figure 1), having either a conical or tapered tip (Figures 1 and 2) and being angled at about 90. Gerstel et al disclose in column 8, lines 30-60, column 9, lines 29-35 and column 10, lines 55-column 11, lines 63 that the microneedles can be made of a material consisting of a metal, and metal alloy, a biodegradable polymer or a non-biodegradable polymer Gerstel et al disclose in column 8, line 60-column 9, line 41 and column 11, lines 20-51 the microneedles can be formed by a micromachining technique selected from lithography, etching, thermal oxidation of silicon, electroplating, electroless plating, diffusion, ion implantation, film deposition, sputtering, chemical vapor deposition, epitaxy, or anodization.

Gerstel et al disclose the claimed invention except for the substrate being formed from a flexbile material. Thompson teaches in Figure 8 that it is known to use a medical device having a flexible substrate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Gerstel et al with a flexible substrate as taught be Thompson, since such a modification would allow for easier securement of the device to a user's skin.

3. Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al as modified by Thompson in view of Eicher et al (US 6,132,755).

Gerstel et al as modified by Thompson disclose the claimed invention except a transport control mechanism for generating a voltage field gradient for causing the material to move across a biological barrier. Eicher et al discloses a transport control mechanism for generating a voltage field gradient for causing the material to move across a biological barrier in column 5, lines 48 – column 6, line 8. It would have been obvious to one with ordinary skill in the art to modify the system as taught by Gerstel et al as modified by Thompson with a transport control mechanism for generating a voltage field gradient for causing the material to move across a biological barrier as taught by Eicher et al since such a modification would increase the migration of the drug across the skin barrier and improve absorption.

4. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al as modified by Thompson in view of Godshall et al (US 5,879,326).

Gerstel et al as modified by Thompson disclose the claimed invention except a transport control mechanism for generating an ultrasonic force gradient for causing the material to move across a biological barrier. Godshall et al discloses a transport control mechanism for generating an ultrasonic force gradient for causing the material to move across a biological barrier in column 2, lines 7-16. It would have been obvious to one with ordinary skill in the art to modify the system as taught by Gerstel et al as modified by Thompson with a transport control mechanism for generating an ultrasonic force gradient for causing the material to move across a biological barrier as taught by Godshall et al since such a modification would increase the migration of the drug across the skin barrier and improve absorption.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cw

10/26/05

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER